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09/330,384	06/11/1999	RICHARD E. GLIKLICH	OSC99-01	9339

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EXAMINER	
RIMELL, SAMUEL G	
ART UNIT	**PAPER NUMBER**
2164	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/330,384	GLIKLICH, RICHARD E.	
	Examiner	Art Unit	
	Sam Rimell	2164	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,12-18,20-23,25-29,32-35,37,38 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42* is/are allowed.

6)☒ Claim(s) *1-2, 5-10, 12-18, 20-23, 25-29, 33, 35, 37, 38, 40, 41, 43* is/are rejected.

7)☒ Claim(s) *32 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 41: Claim 41 calls for the comparison of a privilege level of a first user with the privilege level of a second user. This feature does not reside in the original specification. Applicant argues that the feature is presented on page 22, lines 13-27, but no recitation of this feature is found on page 22, or at any other point in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43: The last two lines refer to "the use with the higher privilege level", where the word "use" apparently should be "user". Correction is required. Interpretation of the claim was made with the assumption that the intended word was "user".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10, 12, 13, 20-23, 25-29, 33, 37-38 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by DeBusk et al. (U.S. Patent 5,991,728).

Claim 10: FIG. 4 discloses the step of obtaining an identification of a user (Login) and a privilege level (password). Each password of each user is definable as a distinct privilege level. FIG. 13 illustrates a search template which permits the selection of medical studies, which are primarily studies on the usage of pieces of surgical equipment. The user enters the desired study and other information, such as which doctors are to be compared in the study. FIG. 14 illustrates the clinical outcome and provides a comparison study between two doctors. The doctor comparison is based upon usage of medical equipment, but may also be based upon comparisons of those same doctors of "consumable medical supplies" (col. 29, lines 64-65) which includes the prescription of drugs by physicians. Any given user logged into the system can view any portion or all portions of the clinical outcome report by merely reading a portion of the report or the entire report. It is noted that the term "viewing" only pertains to what the user desires to look at and does not require any specific limitations on what the algorithm actually presents to the user.

Claim 12: FIG. 14 shows the user as being presented with a list of medical studies (two studies). The selection of the studies is based upon the input into the template of FIG. 13. The privilege level is associated with the display of data, as users who do not have a password have a lower privilege level and thus do not view nay data, whereas users who do have a password have a higher privilege level and can view the display of FIG. 14. The last paragraph of claim 12 is entirely prefaced by "when" clauses and thus is entirely optional. Optional claim limitations are

not necessarily exercised, and thus not limiting the claim unless positively claimed as being exercised.

Claim 13: FIG. 14 illustrates the comparison of doctors for the treatment of an ailment by surgery.

Claim 20: FIG. 7 illustrates the inputting and logging of medical information, which corresponds to receiving sets of medical information having specific values. When the log/save button (192) is pressed, the data is maintained. FIG. 4 illustrates the step of obtaining a password (Login) and privilege level (password). FIG. 13 illustrates a template for allowing a user to make selections of multiple characteristics (equipment types) and multiple doctors. Using a clinical algorithm, the display chart of FIG. 14 is produced, which compares a doctor to another doctor on the usage of medical equipment. The comparison can also be made for "consumable medical supplies" (col. 29, lines 64-65) which includes drugs. The display output is dependent upon the user having a password, which is considered to be a specific privilege level. What the user decides to "view" is dependent upon the desires of the user. A given user may view a portion of or all of the reports. The term "view" does not limit the content of what the program actually produces as output to the user.

Claim 21: See remarks for claim 20, note that the clauses prefaced by the word "when" are optional, and thus do not limit the claim since they are not required to be exercised. The "ranking" of the characteristic is the "% expectancy" shown in FIG. 14. The forms of feedback are reports such as FIG. 14, which are used in hospital supply management. Col. 7, lines 34-35 state that these are used for standardizing procedure resource allocation, which means the information will effect the types of equipment used during treatments such as surgery.

Claim 22: The ranking of "% expectancy" is also a risk assessment of non-conformance. Conformance is 100% of expectancy, and the percent expectancy shows how far off the physician is from that conformance mark.

Claim 23: In Debusk et al., a "trigger event" is any display of non-conformance, such as the display of 66% expectancy by Dr. Gary Bernard, which is nonconforming. The notification of the trigger event is made to the medical professional viewing the chart.

Claim 25: The % expectancy in each line of FIG. 14 is a comparison of an answer related to a person (a physician) to a typical answer (the normal standard for a physician). The answer is the number of a particular supply type used and the typical answer is the normal number of that particular supply which is used. The comparison results in a numerical value, such as "66%" which is a ranking of how well that physician conforms to the standards of using that particular supply.

Claim 26: The particular person is a physician. The person has a defined privilege level, namely, a password, or no password. A user having a password privilege level can view the results of FIG. 14 which compares at least two physicians.

Claim 27: The answers illustrated in FIG. 14 are shown as being explicitly related to physicians, but are also indirectly related to patients, since the supplies being illustrated are ultimately used on patients. The ranking ("% expectancy") also corresponds to a level of treatment since a usage of surgical supplies corresponds to an invasive surgical level of treatment, as opposed to other non-invasive levels of treatment.

Claim 28: See remarks for claim 20-21.

Claim 29: FIG. 14 illustrates the display of two sets of medical information which relate to physicians. The information is not displayed unless the user has the privilege level of having a password. The information shown in FIG. 14 illustrates the comparison of one physician against another.

Claim 33: FIG. 14 is a display involving a comparison of doctors in the treatment of a patient by C-section. Functions (ii)-(iv) are optionally recited and carry no patentable weight.

Claim 37: FIG. 14 is an example of a clinical outcome. Col. 7, lines 34-35 state that these outcomes are used for standardizing procedure resource allocation, which means the information will effect the types of equipment used during surgical procedures.

Claim 38: FIG. 32 of DeBusk discloses an input screen in which a user has entered a medical study selection (492---Perfusion Tracepak) and patient medical condition data (box 494—"inner ear lesion"). The two types of data are correlated in order to produce outcome reports, such as those of FIGS. 14-16. The "clinical outcome" is the usage of specific amounts of surgical supplies during surgical procedures on patients and are presented in the reports of FIGS. 14-16.

Claim 40: All of the studies (FIGS. 14-16) have clinical outcomes (results of supply usage). Any study may be selected from the database.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Edelson et al. (U.S. Patent 5,737,539).

Claim 10: Edelson et al. discloses the concepts of obtaining an identification of a user and privilege level by obtaining a password (col. 10, lines 19-30). Any given user logged into the system can all or a portion of the presented report by merely reading all or a portion of the report. It is noted that the term "views" or "viewing" only pertains to what the user desires to look at, and not what the algorithm is actually configured to present. FIG. 2 is a selection template which allows a user to select a particular medical study. Each individual patient record is considered to be a medical study. FIG. 3 illustrates the entry of medical data into each medical study. A clinical algorithm is used for a variety of functions, primarily to display data. One clinical outcome is the display chart shown in FIG. 13, which illustrates a comparison of performance of one physician to another physician. The two physicians compared are the Diagnosing physician and the Resolving Physician, the performance which is recorded is the date the particular physician saw the patient. The clinical data such as show in FIG. 13 is only output to a user having a password. A password is considered to be a higher privilege level and an individual who does not have a password is considered an individual who has a lower privilege level.

Claim 14: The patient's current medical history is produced in section 43 of FIG. 3. This current medical history is produced by asking the patient questions and obtaining an answer and repeating the process until a complete history is obtained.

Claim 15: FIG. 11 illustrates a scenario where data produced from the patient's medical history or input by the physician does not conform to a standard. The trigger event is a pop-up warning about a particular drug, indicating that the drug does not conform to a standard.

Claim 16: The trigger event can be processed based upon data entered by the doctor or provided by the patient in the medical history. After the trigger event is resolved, the doctor can prepare a prescription for the patient (button 80 in FIG. 3).

Claim 17: If the trigger event occurs for a drug that the patient has described as currently in use, the notification would also have to be made to the patient to stop using the medication. The doctor may then prescribe a different more preferred medication.

Claim 18: The trigger event occurs when any non-conforming prescription data is presented, which can occur at any time ("timing of data entry"). The physician can then change the prescribed medication and present a new prescription to the patient as a result of the trigger event.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 5-9 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debusk et al. (5,991,728) or Edelson (5,737,539) in view of applicant's admission of obviousness.

Claims 1-2, 5-9 and 35: In conjunction with the interview of 4/20/04, claims 1-2, 5-9 and 35 have been examined on the merits. These are the claims remaining from applicant's

originally non-elected group II. Since applicant has admitted obviousness between the groups in the remarks of 5/3/04, the claims must be examined on the merits.

However, MPEP 809.02 and MPEP 2145 state that such admission may trigger a statutory grounds of rejection under 35 USC 103(a).

MPEP 809.02 states: *"Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention".*

MPEP 2145 states: *"Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection."*

Since the attorney arguments present an admission of obviousness between all the claims of group I and the remaining claims of group II, and since the claims of group I have been rejected, the claims of group II are rejected as being obvious variants of the claims of group I, by applicant's direct admission of such fact. Applicant's admission is considered prima facie evidence of obviousness.

Claims 32 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 43 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claim 42 is allowed.

Remarks

Each of the independent claims which are rejected by either DeBusk et al. or Edelson et al. (claims 1, 6, 10, 20, 21, 28 and 38 have been amended to define the determination of a relative privilege level of a user. Examiner maintains that this feature is taught by both DeBusk et al. and Edeleson et al. by their teaching of a requirement for entry of a password. When a user is required to enter a password into a computing system, the computing system determines whether the password is accepted, and thus determines whether the user has a defined privilege level on that system. The privilege levels are relative, in that a user without a password has no privilege level and user with a password has at least some privilege level. The user with the password thus has a higher privilege level than a user without a password, so the two different privilege levels are relative to one another.

The current amendment also proposes to add claims 41-43. Claim 41 is found to contain new matter, as described at the beginning of this action. Claim 42 is allowed, and claim 43 is rejected on a minor formality, but indicated to contain patentable subject matter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (571) 272-4084.

Sam Rimell
Primary Examiner
Art Unit 2164